

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date  
15 July 2004 (15.07.2004)

PCT

(10) International Publication Number  
**WO 2004/058040 A2**

(51) International Patent Classification<sup>7</sup>: **A61B**

(21) International Application Number: **PCT/EG2003/000014**

(22) International Filing Date:  
27 December 2003 (27.12.2003)

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:  
2002121401 28 December 2002 (28.12.2002) **EG**

(71) Applicants and  
(72) Inventors: HASSANIEN, Ali, Mohamed, Ali [EG/EG]; 131 Ahmed Shawky Street, Roshdy, Alexandria (EG). AL-TAHER, Ali, Sulaiman, Murad [AE/AE]; P.O. Box 97555, Dubai (AE).

(74) Agent: EL DEKKI, Ragail; Ragail El Dekki & Partners, P.O. Box 452, Sidi-Gaber, Alexandria (EG).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

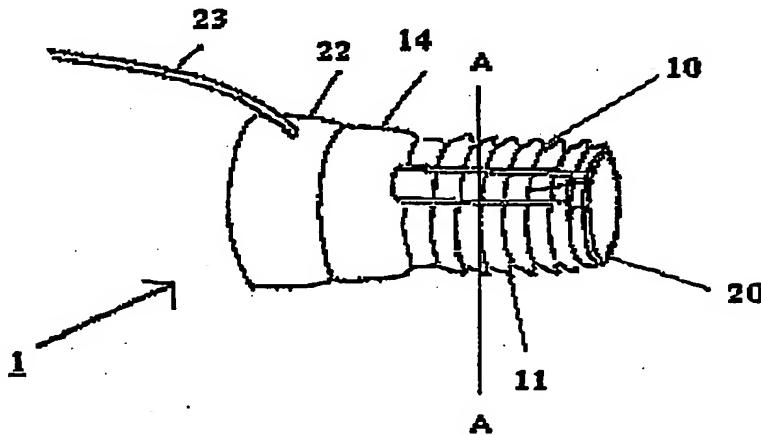
— of inventorship (Rule 4.17(iv)) for US only

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DISPOSABLE DEVICE FOR MULTI-LIGATION OF BLEEDING ESOPHAGEAL VARICES



(57) Abstract: The present invention relates to device for treating bleeding esophagus. The said device consists of three parts of cylinders. The first part characterized by its interior 2/3 is in the form of toothed rows with equal dimensions and parallel to each other along its circular surface. Its posterior 1/3 is in the form of two cylinders inside each other and connected together at its junction with the anterior 2/3 part leaving a specific space in between. The second part represent part of cylinder with three toothed arms situated vertically on it and similar in shape and dimensions. The third part consists of two cylinders inside each other and connected together on one side and free on the other side to be compatible with the other parts.

WO 2004/058040 A2

6/PDS

JC20 Rec'd PCT/PTO 27 JUN 2005

**Disposable Device for multi-ligation of bleeding  
Esophageal varices.**

**Technical field:**

This invention relates to disposable device for ligation of bleeding Esophageal varices. In particular the invention directed to a new disposable device for the ligation of bleeding Esophageal varices characterized in that it has a new mechanism and can be used for multi-ligation of the Esophageal varices.

**Background of the invention:**

Bleeding Esophageal varices is a severe complication of various liver diseases as a result of the high venous pressure on the esophageal region. The main diseases that lead to the Bleeding Esophageal varices includes :

- 1 - Liver parasites such as Bilharzias
- 2 - Various kinds of Hepatitis.
- 3 - Liver fibrosis of various origin ( e.g. from drugs, alcohol liver toxicity etc. )

Due to the high venous pressure on the esophageal region, hemorrhoids start to develop and immediately bleeding occurs. Where bleeding occurs, there is a need to achieve hemostasis in bleeding varices and minimize recurrence of this bleeding which may lead eventually to death..

Presently, these Bleeding Esophageal varices are treated by any of the following methods :

- 1 - by pass surgery to redirect the main veins and reduce pressure in the esophageal region.
- 2 - Injection sclerotherapy using endoscope.
- 3 - band ligation utilizes an endoscope.

Prior Art :

Currently, therapeutic techniques includes injection sclerotherapy and band ligation. These techniques are utilized for the immediate and long term control of hemorrhaging associated with esophageal varices.

In sclerotherapy, a solution, such as sodium morrhuate or ethanolamine is injected submucosally, utilizing endoscope, into the tissue around the varicose vein in the esophagus to cause inflammation and scarring to close off the vein and reduce the likelihood of bleeding.

Disadvantages of these methods include the following :

- 1 - It needs experienced surgeon to handle the injection , to avoid injected the material in non-target regions.
- 2 - Some of the bleeding veins can not be handled by this process .
- 3 - repeated injection may create ulcerations or fibrosis which can lead to esophageal strictures .

Ligation is effective method to treat this case using endoscope. The esophageal varices are snared with elastic bands to eradicate the varices.

Presently, there is a device for effecting this kind of ligation, this device is working through a mechanism that includes pulling the varices to the unit and release the rubber band by pulling a string .

The use of this device is very critical since it may cause a damage to the endoscope itself and releasing of one rubber band only depend on the pulling forces if it too strong two or more rubber bands may be released.

Other ligation devices are known but the can be used to ligate only one varices at a time and then has to be taken

out and reloaded which is inconvenient for both of the patient and the surgeon.

In US patent 5,707,355, Zimmon ; a method and apparatus for treating esophageal varices and mucosal neoplasm. In this method, a balloon tamponade device is utilized to deliver a dressing containing a sclerosant agent to bleeding esophageal.

US Patent No.5,400,770 , Nakao et al, disclosed a surgical device for use with endoscope to perform gastroesophageal hemostasis operations. The device comprises an insertion member , inflatable balloon and attachment component.

US patent 6,139,527, Laufer et al, disclose a method and apparatus for treating hemorrhoids wherein a catheter delivers an electrode within a vein for a minimally invasive treatment of hemorrhoids using RF energy.

Yet a need exists in the art to treat the bleeding veins which give rise to esophageal varices and reduce venous pressure on the esophageal region from the portal vein system without the attendant risks of invasive surgery. Further need exists to provide a less invasive procedure which can treat multiple venous sites quickly and easily. There is still a need to achieve hemostasis in bleeding varices and minimize recurrence of bleeding.

**Brief Description of the drawings :**

Fig 1 is schematic perspective view showing the new device of the invention.

Fig 2. schematic perspective view showing the threads.

Fig 3 cross sectional view showing the components of the cylinder.

Fig 4. Cross sectional taken along the line A-A of fig 1..

Fig 5. schematic end view of the cylinder showing the position of the three arms.

Fig 6. Cross sectional view showing the position of the pressure tube.

**Detailed Description of the invention:**

The present invention relates to device for multi-ligation of bleeding Esophageal varices. The new device will be better explained with reference to the accompanying drawings.

As illustrated in Fig 1 , the device ( 1 ) consists of three main parts. The first part is a cylinder ( 10 ) characterized in that the first two thirds of this cylinder is threaded . Threads ( 11 ) are circumscription and as shown in Fig ( 2 ) it has a right angled triangle cross section . wherein the altitude ( 12 ) of the said triangle upwardly positioned. Distances and dimensions of all threads are identical. Cutting these threads longitudinal , three identical equally spaced grooves in the form of passageways allowing tongues to pass through as better shown in Fig 4 which is cross section taken along line A-A of Fig 1 .

The last third of the cylinder ( 10 ) is not threaded and covered by another cylinder ( 14 ). Both cylinder having equal length , however, cylinder ( 14 ) is bigger in diameter. Cylinders 10 and 14 are integrated completely except for the position of the three grooves ( 13 ). Fig three represent a cross section of the two unified cylinders ( 10) and ( 14 ) .

The second part is shown in Fig 5 and consists of a base cylinder ( 16 ) having three arms ( 17 ) . The arms ( 17 ) having threads ( 18 ) which are identical in all respects with threads ( 11 ) of the first part of the device. And having unthreaded part ( 21 ) connecting the threaded arms with the base cylinder. Dimensions of the arms ( 17 ) adopted to fit in the grooves ( 13 ) easily and to form altogether homogeneous unit with the first part. The base cylinder ( 16 ) is introduced in the space created by the last third of cylinder ( 10 ) and cylinder ( 14 ) so that arms can be inserted in the grooves and base cylinder moves upwardly in the said space and the arms ( 17 ) emerge and appeared on the surface of the threaded part of cylinder ( 1 ) and integrated therewith so that when arm ( 17 ) reach the top part of the device ( 20 ) the threads of the cylinder ( 10 ) are completed by the threaded arms ( 17 ) . Within the unthreaded part on the arm ( 17 ) , there is a special spring ( 19 ) which is used to trigger the arms upwardly and return it back after triggering.

Fig 6 represents the third part of the device which consists of two uni-center cylinders ( 22 ) and ( 23 ) one having bigger diameter ( 23 ) than the other which create a space ( 5 ) in between. There is a micro tube ( 24 ) connected to the said space from one side and connected to pressure source ( not shown in the drawing ) from the other side.

As mentioned above the said device can be easily used to ligate bleeding Esophageal varices using rubber bands loaded inside the device. Number of bands loaded into device can vary from 4 up to 10, preferably from 4 to 8 and most preferable 6 rubber bands.

The practice of the invention is illustrated in the following non-limiting example.

**Exemplary Procedure:**

The device in this example is loaded with 6 rubber bands so that the first rubber band is immediately in front of the three arms.

The unit is connected with the endoscope and inserted into the patient from the mouth up till Esophagae. The surgeon determine the bleeding varices which is withdrawn by the endoscope . Using a small air pressure ( e.g. air pressure created by a syringe ) the surgeon trigger the first rubber band upon using the pressure. Once pressure is used the three arms pushes the first rubber band to ligate the varices already withdrawn and in the mean time the spring return the arms back to the original position releasing a new rubber band to replace the one already used.

We claims,

1 - New disposable device for ligation of bleeding Esophageal varices characterized in that it consists of three main cylindrical parts.

2 - New disposable device for ligation of bleeding Esophageal varices according to claim 1 wherein the first part is a cylinder characterized in that the first two thirds of this cylinder is threaded . The last third of the cylinder is not threaded and covered by another cylinder. Both cylinders having equal length , however, one of them is bigger in diameter. Cylinders are integrated completely except for the position of the three grooves .

3 - New disposable device for ligation of bleeding Esophageal varices according to claim 2 wherein Threads are circumscription and have a right angled triangle cross section wherein the altitude of the said triangle upwardly positioned. Distances and dimensions of all threads are identical.

4 - New disposable device for ligation of bleeding Esophageal varices according to claim 2 wherein threads are cut longitudinal by three identical equally spaced grooves in the form of passageways allowing tongues to pass through.

5 - New disposable device for ligation of bleeding Esophageal varices according to claim 1 wherein the second part consists of a base cylinder having three arms emerging therefrom . The arms having threads which are identical in all respects with threads of the first part of the device, and having unthreaded part connecting the threaded arms

with the base cylinder. Within the unthreaded part of the arm , there is a special spring which is used to trigger the arms upwardly and return it back after triggering.

6 - New disposable device for ligation of bleeding Esophageal varices according to claim 5 wherein threads are identical in all respects with threads of the first part of the device.

7 - New disposable device for ligation of bleeding Esophageal varices according to claim 1 the third part of the device consists of two uni-center cylinders one having bigger diameter than the other creating a space in between. There is a micro long tube connected to the said space from one side and connected to pressure source from the other side.

8 - New disposable device for ligation of bleeding Esophageal varices wherein it can be loaded with a number of rubber bands amounting to 6 or more.

9 - New disposable device for ligation of bleeding Esophageal varices characterized in that one rubber band only can be released each time the device is triggered.

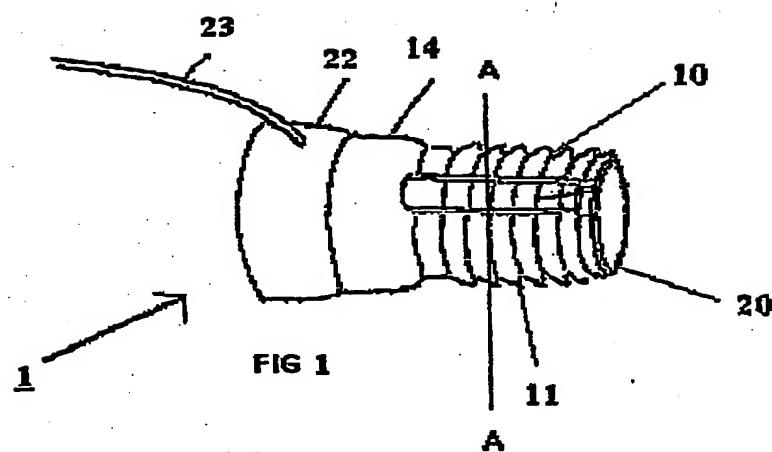
10 - New disposable device for ligation of bleeding Esophageal varices wherein the mechanism of releasing the rubber band depend on a slight pressure created either by air or distilled water.

11 - New disposable device for ligation of bleeding Esophageal varices according to claim 10 wherein the pressure source used can be medical syringe.

12 - New disposable device for ligation of bleeding Esophageal varices substantially as described hereinbefore with reference to the accompanying drawings.

10/540955

1 / 6



10/540955

2 / 6

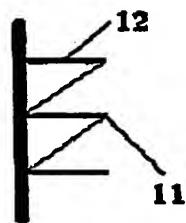


Fig 2

10/540955

3 / 6

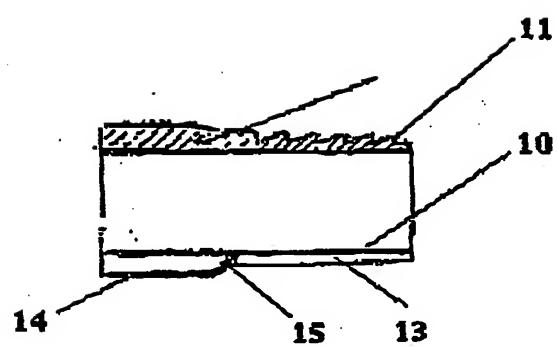
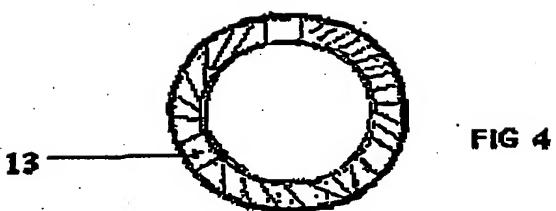


FIG 3

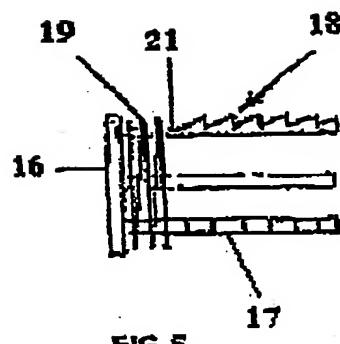
10/540955

4 / 6



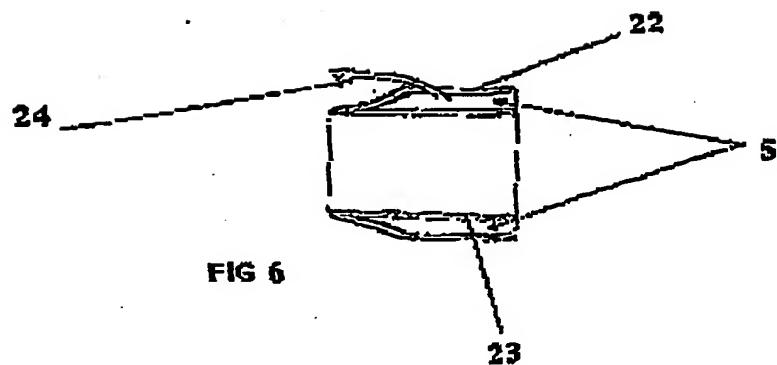
10/540955

5 / 6



10/540955

6 / 6



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date  
15 July 2004 (15.07.2004)

PCT

(10) International Publication Number  
**WO 2004/058040 A3**

(51) International Patent Classification<sup>7</sup>: **A61B 17/12**

LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:  
PCT/EG2003/000014

(84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(22) International Filing Date:  
27 December 2003 (27.12.2003)

Declaration under Rule 4.17:

— *of inventorship (Rule 4.17(iv)) for US only*

(25) Filing Language:

English

Published:

- *with international search report*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(26) Publication Language:  
English

(88) Date of publication of the international search report:  
11 November 2004

(30) Priority Data:  
2002121401 28 December 2002 (28.12.2002) EG

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

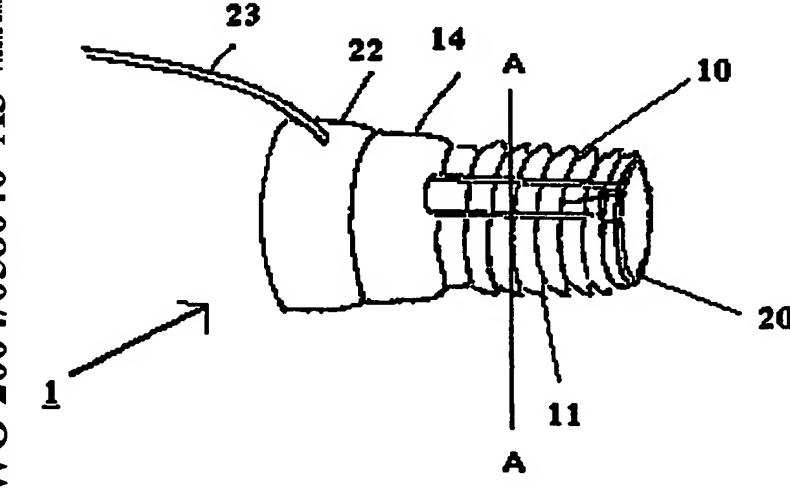
(71) Applicants and

(72) Inventors: **HASSANIEN, Ali, Mohamed, Ali [EG/EG]; 131 Ahmed Shawky Street, Roshdy, Alexandria (EG). AL-TAHER, Ali, Sulaiman, Murad [AE/AE]; P.O. Box 97555, Dubai (AE).**

(74) Agent: **EL DEKKI, Ragai; Ragai El Dekki & Partners, P.O. Box 452, Sidi-Gaber, Alexandria (EG).**

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,

(54) Title: DISPOSABLE DEVICE FOR MULTI-LIGATION OF BLEEDING ESOPHAGEAL VARICES



(57) Abstract: The present invention relates to device for ligation of bleeding esophageal varices. The device consists of three parts of cylinders. The first part (10) characterized by its interior 2/3 is in the form of toothed rows (11) with equal dimensions and parallel to each other along its circular surface. Its posterior 1/3 is in the form of two cylinders (10, 14) inside each other and connected together at its junction with the anterior 2/3 part leaving a specific space in between. The second part (16, 17) represent part of cylinder with three toothed arms (17) situated vertically on it and similar in shape and dimensions. The third part consists of two cylinders (22, 23) inside each other and connected together on one side and free on the other side to be compatible with the other parts (10, 14, 16, 17).

WO 2004/058040 A3

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EG 2003/000014

## CLASSIFICATION OF SUBJECT MATTER

**IPC<sup>7</sup>: A61B 17/12**

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

**IPC<sup>7</sup>: A61B 17/12, 17/128**

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPI

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0679368 A1 (KAB. KAISHA TOP) 2 November 1995 (02.11.1995) <i>the whole document; especially abstract; figures 6,7; column 9, line 31 - column 12, line 5.</i>	1,8,9
A		2-5
X	EP 0893096 A1 (SUMITOMO BAKELITE) 27 January 1999 (27.01.1999) <i>the whole document; especially figures 1a, 1b; abstract; column 3, line 43 - column 5, line 10; column 5, lines 32-41; column 6, lines 33-43.</i>	1,8 - 11
A		7
X	JP 11 169335 A (SUMITOMO BAKELITE) 29 June 1999 (29.06.1999) <i>the whole document; especially figures 1a, 1b.</i>	1,8,10,11
A		9

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents: „A“ document defining the general state of the art which is not considered to be of particular relevance „E“ earlier application or patent but published on or after the international filing date „L“ document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) „O“ document referring to an oral disclosure, use, exhibition or other means „P“ document published prior to the international filing date but later than the priority date claimed	„T“ later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention „X“ document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone „Y“ document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art „&“ document member of the same patent family
--	--

Date of the actual completion of the international search

12 August 2004 (12.08.2004)

Date of mailing of the international search report

2 September 2004 (02.09.2004)

Name and mailing address of the ISA/AT

Austrian Patent Office

Dresdner Straße 87, A-1200 Vienna

Facsimile No. 1/53424/535

Authorized officer

LUDWIG H.

Telephone No. 1/53424/340

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/EG 2003/000014

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP 07 255733 A (YAMAKI KAZUHIKO) 9 October 1995 (09.10.1995) <i>the whole document; especially figure 13.</i>	1,8,9

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/EG 2003/000014

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: 12  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
to a reference to another part of that application as: " .. as described hereinbefore .. drawings" (according to PCT Rule 6.2).
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No. <b>PCT/EG 03/00014-0</b>
---

Patent document cited in search report		Publication date		Patent family member(s)		Publication date	
EP	A	679368		DE	T	69515360T	2000-10-19
				DE	D	69515360D	2000-04-13
				US	A	5569268	1996-10-29
				EP	A	0679368	1995-11-02
				CA	A	2144098	1995-10-27
				JP	A	8010217	1996-01-16
EP	A	893096		US	B	6464685	2002-10-15
				CN	A	1212610	1999-03-31
				EP	A	0893096	1999-01-27
				JP	A	10179596	1998-07-07
				WO	A	9829038	1998-07-09
JP	A	7255733A	2			none	